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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,720	03/20/2001	Mark W. Mellencamp	041303-0138	2610

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EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/812,720	Applicant(s) MELLENCAMP, MARK W.	
	Examiner Shanon Foley	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,10,12-22,27,28,32-35,37,39 and 41-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,10,12-22,27,28,32-35,37,39 and 41-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In paper no. 10, applicant amended claims 2, 14, 32, cancelled claims 7, 9, 11, 36, 38, 40 and added new claims 44-49. Claims 1-6, 8, 10, 12-22, 27, 28, 32-35, 37, 39 and 41-49 are under consideration.

The subject matter previously indicated as allowable is withdrawn. Upon further consideration, new grounds of rejection are required.

Information Disclosure Statement

Applicant states that a summary of the teachings of the Mayr et al. references was supplied in the IDS of 8/27/02. Applicant also provides a summary of the references on page 12 of the response.

Applicant's summary is appreciated and the references have been considered. The examiner is attaching a copy of the IDS to applicant with the Mayr et al. references initialed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 recites the limitation "KyA" in line 1. There is insufficient antecedent basis for this limitation in the claim. To obviate this rejection, it is suggested that applicant delete the limitation "KyA". For purposes of examination, claim 46 is examined as if it properly depends from claim 16 and includes the limitations recited in claim 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macek et al. (US 5,853,715) as evidenced by Lund (US 3,920,811).

Claim 16 is drawn to a vaccine for protecting a horse against diseases associated with EHV-1, EHV-4 or a combination thereof comprising an inactivated EHV-1 and an adjuvant that includes a cross-linked acrylic acid polymer having a viscosity if no more than about 20,000 cPs as a 1.0 wt.% aqueous solution at pH 7.5. Claim 46 specifies that the EHV-1 virus is inactivated with binary ethylenimine.

Macek et al. teach a vaccine for protecting against diseases associated with EHV-1 and EHV-4 comprising an inactivated EHV-1 virus and a polymer adjuvant such as Carbopol 934P®. The EHV-1 virus of Macek et al. is inactivated with binary ethylenimine. See claims 1, 2, 3, 6 and 7.

Macek et al. do not teach that the polymer adjuvants are cross-linked acrylic acid polymers having a viscosity if no more than about 20,000 cPs as a 1.0 wt.% aqueous solution at pH 7.5.

However, Lund teaches that Carbopol® adjuvants are cross-linked acrylic acid polymers, see column 3, lines 47-51. Lund teaches that these polymers have a viscosity that ranges between 500 to 50,000 cps, see column 4, lines 13-18. Lund also teaches that the pH of the

adjuvant solution is between 6.5-7.5 and that the concentration of the adjuvant in the vaccine solution is between 0.5 to 3%, see column 5, lines 45-54 and column 6, lines 5-13.

One of ordinary skill in the art at the time the invention was made would have been motivated to adjust the adjuvant solution within the vaccine of Macek et al. to the appropriate viscosity to ensure adequate potency of the vaccine, see Lund, column 6, lines 15-28, and to ensure that the adjuvant can be easily mixed with the vaccine composition and injected, see column 7, lines 40-65 of Lund. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of combining the appropriate amount of Carbopol® adjuvant taught by Lund with the equine vaccine of Macek et al. by routine optimization methods in the art, see column 4, lines 3-68 and column 5, line 66 to column 7, line 65 of Lund. One of ordinary skill in the art at the time the invention was made would also have had a reasonable expectation of using the concentrations of Carbopol® taught by Lund in the vaccine of Macek et al. because both Lund and Macek et al. teach inactivated equine vaccines comprising Carbopol® adjuvants, see column 8, line 40 to column 9, line 39 of Lund and column 2 line 57 to column 3, line 9 of Macek et al. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 1-4, 12-15, 17, 20, 27, 32, 33, 42-44, 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macek et al. (US 5,853,715), Studdert (US 5,084,271), and Lund (US 3,920,811), as further evidenced by O' Callaghan (US 5,795,578).

Claims 1, 12, 14 and 32 are drawn to a vaccine for protecting a horse against diseases associated with EHV-1, EHV-4 or a combination thereof, comprising a chemically inactivated

EHV-1 KyA virus and an adjuvant that includes cross-linked olefinically unsaturated carboxylic acid polymer. Claims 13 and 32 state that the polymer includes cross-linked acrylic acid polymer. Claims 2, 3, 15, 32, 42, and 48 specify that the EHV-1 KyA virus is inactivated with binary ethylenimine. Claims 4, 20, 33 and 44 are drawn to the vaccine further comprising inactivated EHV-4. Claim 17 is drawn to a method of protecting a horse against diseases associated with EHV-1, EHV-4 or a combination thereof by administering a chemically inactivated EHV-1 KyA and an adjuvant that includes a cross-linked olefinically unsaturated carboxylic acid polymer. Claim 27 is drawn to a kit comprising a dispenser capable of administering a vaccine to a horse and a composition comprising a chemically inactivated EHV-1 KyA virus and an adjuvant that includes cross-linked olefinically unsaturated carboxylic acid polymer. Claim 28 specifies that the dispenser is capable of dispensing its contents as droplets when administered intranasally. Claim 43 states that the cross-linked acrylic acid polymer has a viscosity if no more than about 20,000 cPs as a 1.0 wt.% aqueous solution at pH 7.5.

Studdert teaches a vaccine comprising inactivated equine herpesvirus type 4 and equine abortion virus type 1, see claims 2 and 3. The inactivated equine abortion virus of Studdert is equine herpesvirus type 1, strain KyA, see column 14, lines 56-57 of O' Callaghan.

Studdert does not teach inactivating the equine herpesviruses by binary ethylenimine.

Macek et al. teach a vaccine for protecting against diseases associated with EHV-1 and EHV-4 comprising an inactivated EHV-1 virus and a polymer adjuvant such as Carbopol 934P®. The EHV-1 virus of Macek et al. is inactivated with binary ethylenimine. See claims 1, 2, 3, 6 and 7.

One of ordinary skill in the art at the time the invention was made would have been motivated to inactivate the viruses of Studdert with conventional inactivating agents, such as binary ethylenimine, in the equine herpesvirus vaccine art. Studdert teaches inactivating the equine herpesviruses with beta propriolactone, see column 2, lines 23-25. Macek et al. teach inactivating agents, such as beta propriolactone and binary ethylenimine, are conventional alternatives for inactivating equine herpesviruses, see column 2, line 64 to column 3, line 1. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for inactivating the equine herpesviruses of Studdert with the binary ethylenimine of Macek et al. because Macek et al. teach that beta propriolactone and binary ethylenimine preserve the antigenicity of equine herpesviruses, see column 2, lines 64 to column 3, line 1.

Studdert also does not teach combining a cross-linked olefinically unsaturated carboxylic acid polymer adjuvant with the vaccine or the viscosity of the adjuvant.

Lund teaches that Carbopol® adjuvants are cross-linked acrylic acid polymers, see column 3, lines 47-51. Lund teaches that these polymers have a viscosity that ranges between 500 to 50,000 cps, see column 4, lines 13-18. Lund also teaches that the pH of the adjuvant solution is between 6.5-7.5 and that the concentration of the adjuvant in the vaccine solution is between 0.5 to 3%, see column 5, lines 45-54 and column 6, lines 5-13.

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the aluminum hydroxide adjuvant of Studdert with the Carbopol® adjuvant of Macek et al. and Lund in the equine herpesvirus vaccine of Studdert because Lund specifically teaches that the adjuvant effect of Carbopol® is superior to that of aluminum hydroxide in an inactivated equine vaccine composition, see column 8, line 40 to column 9, line

68. Therefore, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of eliciting a protective immune response in equines with inactivated viruses and Carbopol®, absent evidence to the contrary.

Lund also teaches that Carbopol® adjuvants are cross-linked acrylic acid polymers, see column 3, lines 47-51. Lund teaches that these polymers have a viscosity that ranges between 500 to 50,000 cps, see column 4, lines 13-18. Lund also teaches that the pH of the adjuvant solution is between 6.5-7.5 and that the concentration of the adjuvant in the vaccine solution is between 0.5 to 3%, see column 5, lines 45-54 and column 6, lines 5-13.

One of ordinary skill in the art at the time the invention was made would have been motivated to adjust the Carbopol® adjuvant of Lund or Macek et al. within the vaccine of Studdert to the appropriate viscosity to ensure adequate potency of the vaccine, see Lund, column 6, lines 15-28, and to ensure that the adjuvant can be easily mixed with the vaccine composition and injected, see column 7, lines 40-65 of Lund. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of combining the appropriate amount of Carbopol® adjuvant taught by Lund or Macek et al. with the equine vaccine of Studdert by routine optimization methods in the art, see column 4, lines 3-68 and column 5, line 66 to column 7, line 65 of Lund. One of ordinary skill in the art at the time the invention was made would also have had a reasonable expectation of using the concentrations of Carbopol® taught by Lund or Macek et al. in the vaccine of Studdert because both Lund, Macek et al. and Studdert teach inactivated equine vaccines comprising adjuvants, see column 8, line 40 to column 9, line 39 of Lund, claim 4 of Studdert and claim 7 of Macek et al.

Studdert also teach injecting the vaccine intramuscularly or sub-cutaneously, see claim 7. The injection taught by Studdert requires the facilitation of a devise to administer the vaccine. Therefore, the components of the kit in instant claim 27 is rendered prima facie obvious in view of the combined inactivated vaccine components and adjuvant of Studdert, Macek et al. and Lund.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 5, 6, 8, 10, 21, 22, 34, 35, 37, 39, 45, 47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macek et al., Studdert, Lund, as further evidenced by O' Callaghan as applied to claims 1-4, 12-15, 17, 20, 27, 32, 33, 42-44, 46 and 48 above, and further in view of Brown et al. (US 4,500,513).

The claims are drawn to the vaccine further comprising inactivated equine influenza virus subtypes A1 and A2.

See the teachings of Macek et al., Studdert, Lund and O' Callaghan above. None of the references teach inactivated equine influenza virus subtypes A1 and A2.

However, Brown et al. teach inactivated equine influenza virus subtypes A1 and A2, see claims 1, 4, 7, 8 and column 10, lines 39 to column 11, line 30.

One of ordinary skill in the art at the time the invention was made would have been motivated to include the inactivated influenza viruses of Brown et al. into the vaccine of Macek et al., Studdert, Lund and O' Callaghan above to protect horses against influenza virus infection, see the previous citations of Brown et al. One of ordinary skill in the art at the time the invention

was made would have had a reasonable expectation for combining the vaccine of Brown et al. with the vaccine of Macek et al., Studdert, Lund and O' Callaghan because the inactivated equine vaccines are all administered multivalently in the same intramuscular administration and use the same Carbopol® adjuvant, see the previous citations of Studdert Macek et al., Lund and O' Callaghan, as well as column 10, lines 22 column 11, line 30 of Brown et al.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 18, 19 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macek et al., Studdert, Lund, as further evidenced by O' Callaghan as applied to claims 1-4, 12-15, 17, 20, 27, 32, 33, 42-44, 46 and 48 above, and further in view of Letchworth, III et al. (US 5,462,734).

Claims 18 and 19 are drawn to a method of administering the vaccine by parenterally administering the vaccine in the first step and intranasally administering the vaccine in a subsequent step. Claim 28 is drawn to intranasally administering the vaccine with a dispenser.

See the teachings of Macek et al., Studdert, Lund, as further evidenced by O' Callaghan. None of the references teach administering the vaccine in the first step and intranasally administering the vaccine in a subsequent step or a dispenser for intranasal administration.

However, Letchworth, III et al. teach parenterally administering a herpesvirus vaccine and subsequently boosting with an intranasal administration, see column 3, lines 39-48. A device for intranasal administration would be obvious in view of the teachings of Letchworth, III et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to administer the vaccine of Macek et al., Studdert, Lund and O' Callaghan by the method of Letchworth, III et al. to induce a systemic and mucosal immunity to the herpesvirus, see the previous citations of Letchworth, III et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of administering the vaccine of Macek et al., Studdert, Lund and O' Callaghan with the method of Letchworth, III et al. because all of the vaccine comprise herepesvirus glycoproteins combined with an adjuvant to augment the immune response.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macek et al., Studdert, Lund and O' Callaghan as applied to claims 1-4, 12-15, 17, 20, 27, 32, 33, 42-44, 46 and 48 above, and further in view of Kit et al. (US 5,2921,653)

The claim is drawn to the vaccine comprising gentamicin.

See the teachings of Macek et al., Studdert, Lund and O' Callaghan above. None of the references teach gentamicin.

However, Kit et al. teach that gentamicin is conventionally used as a preservative in EHV-1 vaccines, see column 26, lines 23-45.

One of ordinary skill in the art at the time the invention was made would have been motivated to use a conventional EHV-1 preservative with a reasonable expectation of success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
July 28, 2003